



**UNITED STATES DEPARTMENT OF COMMERCE**  
**Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

*SR*

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/972,301	11/18/97	COLEMAN	T 325800-588 (P)

022195  
HUMAN GENOME SCIENCES INC  
9410 KEY WEST AVENUE  
ROCKVILLE MD 20850

HM22/0617

EXAMINER	
KEMMERER, E	
ART UNIT	PAPER NUMBER
1646	<i>10</i>

DATE MAILED: 06/17/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/972,301

Applicant(s)

Coleman et al.

Examiner

Elizabeth C. Kemmerer

Group Art Unit

1646



☒ Responsive to communication(s) filed on 31 Mar 1999

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 57-61, 71, 74, 77, and 78 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 57-61, 71, 74, 77, and 78 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1646

## **DETAILED ACTION**

### ***Status of Application, Amendments, And/Or Claims***

The amendment filed 31 March 1999 (Paper No. 9) has been entered in full. Claims 1-56, 62-70, 72, 73, 75 and 76 are canceled. Claims 57-61, 71, 74, 77 and 78 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Withdrawn Objections And/Or Rejections***

The rejection of claims 57, 59, 60, 62, 64, 65, 67, 68 and 70-76 under 35 U.S.C. § 112, first paragraph, regarding new matter, as set forth at p. 3 of the previous Office Action (Paper No. 8, 01 February 1999) is *withdrawn* in view of the amendments (Paper No. 9, 31 March 1999).

The rejection of claims 65-70, 72, 73, 75 and 76 under 35 U.S.C. § 112, first paragraph, as set forth at pp. 3-4 of the previous Office Action (Paper No. 8, 01 February 1999) is *withdrawn* in view of the canceled claims (Paper No. 9, 31 March 1999).

The rejection of claims 65-67, 72 and 75 under 35 U.S.C. § 112, second paragraph, as set forth at p. 8 of the previous Office Action (Paper No. 8, 01 February 1999) is *withdrawn* in view of the canceled claims (Paper No. 9, 31 March 1999).

Art Unit: 1646

The rejection of claims 68-70, 73 and 76 under 35 U.S.C. § 102(e) as set forth at p. 9 of the previous Office Action (Paper No. 8, 01 February 1999) is *withdrawn* in view of the amended and canceled claims (Paper No. 9, 31 March 1999).

***35 U.S.C. § 112, First Paragraph***

Claims 57-61, 71, 74, 77 and 78 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The basis for this rejection is set forth at pp. 6-7 of the previous Office Action (Paper No. 8, 01 February 1999).

Applicant argues (pp. 3-4, Paper No. 9, 31 March 1999) that the claims have been amended or canceled to obviate the rejection. This has been fully considered but is not deemed to be persuasive. The claims are directed to isolated polypeptides comprising the amino acid sequence of SEQ ID NO: 2, the polypeptide encoded by ATCC Deposit 97165, and fragments thereof at least 30 contiguous amino acids in length. Dependent claims 71 and 74 are directed to fusion proteins comprising these polypeptides and compositions comprising these polypeptides plus a pharmaceutically acceptable carrier. The specification discloses EMAP III which has the structure of 1-168 of SEQ ID NO: 2 or is encoded by the deposited human cDNA clone. EMAP III shares significant sequence identity with a polypeptide known as EMAP II. Based on this sequence identity, the specification speculates that EMAP III has similar biological activities to EMAP II. No biological

Art Unit: 1646

activities have been specifically demonstrated for EMAP III. The assertion that EMAP III has similar biological activities as EMAP II cannot be accepted in the absence of supporting evidence, because the relevant literature reports examples of closely related polypeptides belonging to a polypeptide family wherein individual members have distinct, and sometimes even opposite, biological activities. See Vukicevic et al. and Pilbeam et al., of record. Thus, the specification fails to teach the skilled artisan how to use EMAP III and variants thereof without resorting to undue experimentation to determine what the specific biological activities of EMAP III are.

The specification does not teach the skilled artisan how to use the disclosed EMAP III for purposes unrelated to the asserted biological activity. For example, there is no evidence of tissue-specific expression patterns, such that the EMAP III protein could be used as a tissue-specific marker. Similarly, there is no disclosure of particular disease states correlating to an alteration in levels or forms of EMAP III such that EMAP III could be used as a diagnostic tool. Therefore, the skilled artisan is not provided with sufficient guidance to use the claimed polypeptides or any purpose.

Due to the large quantity of experimentation necessary to determine an activity or property of EMAP III such that it can be determined how to use EMAP III, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, and the state of the prior art establishing that biological activity cannot be predicted based on structural similarity, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Art Unit: 1646

***Sequence Rules***

The application remains not fully in compliance with the sequence rules, 37 CFR 1.821-1.825, because each disclosure of a sequence embraced by the definitions set forth in the rules is not accompanied by the required reference to the relevant sequence identifier (i.e., SEQ ID NO). This occurs at least at p. 32. See previous Office Action, Paper No. 8, 01 February 1999. A Notice of Allowability cannot be issued until the application is in sequence rules compliance.

***Conclusion***

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1646

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D., whose telephone number is (703) 308-2673. The examiner can normally be reached on Mondays through Thursdays from 6:30 a.m. to 4:00 p.m. The examiner can also normally be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached on (703) 308-4310.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

*Elizabeth C. Kemmerer*

ELIZABETH KEMMERER  
PRIMARY EXAMINER

ECK  
June 16, 1999